SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6161–6200

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not labeled as prescribed therein; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6161. Allure bust development device. (F.D.C. No. 44114. S. No. 26–112 R.)

QUANTITY: 1 device at Lompoc, Calif.

SHIPPED: 1–17–60, from Alamogordo, N. Mex., by Mrs. Patra Roland.

LABEL IN PART: (Metal plate on device) "Allure Mfd. by Allure Incorporated, Hollywood, Calif., Model 31358, Serial No. 1032."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or pump operated by an electric motor. Attached to the compressor was a pressure regulator, a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups.

While in use, the plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation.

The air compressor and accessory equipment were contained in a metal cabinet 36" x 22" x 18".

LIBELED: 4–5–60, S. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for developing the human breast; and 502(j)—the labeling of the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in the labeling thereof.

DISPOSITION: 5–10–60. Default—destruction.

6162. Ray of Life device. (F.D.C. No. 44011. S. No. 51–138 P.)

QUANTITY: 11 devices at St. Paul, Minn., and 2 devices at Stillwater, Minn., in possession of Henry Amundson.

SHIPPED: 5–20–58, from Racine, Wis.

LABEL IN PART: "Electronic High Frequency Generator * * * The Ray of Life."

RESULTS OF INVESTIGATION: The device was a type of electronic high-frequency generator which produced a glow discharge in a variety of gas-filled glass applicators.

LIBELED: 12–29–59, Dist. Minn.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 502(j)—the article was dangerous to health when used as directed.

DISPOSITION: 3–23–60. Consent—claimed by Henry Amundson, Stillwater, Minn., and dismantled.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6163. Les-Wate capsules. (F.D.C. No. 44370. S. No. 85–084 P.)

QUANTITY: 5 cans, 5,000 capsules each, and 8 display cartons, each containing 4 30-capsule btls., at Baltimore, Md., in possession of Reyman Drug Co., Inc.

SHIPPED: 1–29–60, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Can) "Phenylpropanolamine HCl Prolongsuls Each Prolongsul contains: Phenylpropanolamine HCl 75 mg. * * * Caution: Federal law prohibits dispensing without prescription. Lot No. 9919 Richlyn Laboratories, Philadelphia, Pa.," (btl.) "Les-Wate Capsule-A-Day to Melt Fat away Les-Wate Laboratories, Baltimore, Md. Distributor * * * Each capsule contains: Phenylpropanolamine HCl. 75 mg. released gradually and equivalent to 3 doses over a period of approximately 8 hours."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and relabeled by the dealer from bulk stock shipped as described above.

LIBELED: 3–9–60, Dist. Md.

CHARGE: 502(a)—while held for sale, the name "Les-Wate" and other statements on the label of the article contained false and misleading representations that the article was effective for weight reduction; 503(b)(4)—when shipped, the label bore the statement "Caution: Federal law prohibits dispensing without a prescription" and the article was a drug not subject to section 503(b)(1); and 505(a)—the article was a new drug and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 4–1–60. Default—destruction.